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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 23, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Lincoln Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, or by e-mail at smt@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

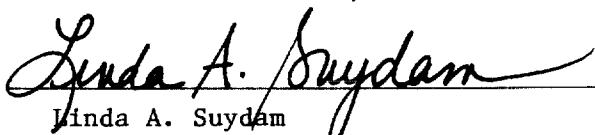
Agenda: On September 23, 1999, from 8:30 a.m. to 1:30 p.m., the committee will hear formal presentations followed by public participation in a discussion of keratomes. Public participants in the group discussion are requested to develop a comprehensive list of problems associated with keratomes, the related causes, and the steps that can be taken to mitigate the problems. From 1:30 p.m. to 5 p.m., the committee will discuss issues related to defining the scope and purpose of a proposed keratome guidance to be developed from an outline of contents currently

recommended for keratome premarket notification submissions. Single copies of the outline are available to the public by contacting the person noted above.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 7, 1999. Formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 10:15 a.m. on September 23, 1999. Those desiring to make formal oral presentations should notify the contact person before September 10, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Those desiring to be a participant in the open group discussion should notify the contact person by September 10, 1999, to reserve a place at a discussion table.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.
2).

Dated: August 23, 1999


Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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